

REMARKS

Claims 1-33 were presented for consideration in the present application. The present amendment cancels claim 22 and adds new claim 34. Thus, claims 1-21 and 23-34 are presented for consideration upon entry of the present amendment.

The Office Action states that claims 2, 6, 7, 12 and 24 are objected to because of informalities. Claims 2, 6, 7, 12 and 24 have been amended as suggested by the Examiner. Applicant respectfully requests reconsideration and withdrawal of this objection.

Claims 2 and 22 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 2 has been amended to clarify the phrase "said fibers are aligned to more than 50, preferably more than 90%". Claim 22 has been canceled. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,626,950 to Brown et al. (hereinafter "Brown"). Applicant respectfully traverses this rejection.

Independent claim 1 provides, in part, a prosthetic device having at least one layer comprising at least partially oriented fibers, a base component and a stabilization area, wherein the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device and form a brush-like structure.

Independent claim 30 provides, in part, a prosthetic device having at least one layer comprising at least partially oriented fibers, a base component and a stabilization area, wherein the fibers are aligned essentially perpendicularly to a top surface of the base component facing the fibers.

Independent claim 31 provides, in part, a prosthetic device having at least one layer comprising fibers, a base component, and a cell barrier layer provided between the at least one layer comprising fiber and the base component.

Brown relates to the field of tissue repair and the use of composite scaffold implants and scaffold fixation devices. Brown provides for an implant consisting of a foamed polymer and a ceramic base component. It is clear that the polymeric portion of the implant is a porous polymer produced by a foaming process. In particular, the foam used in Brown is preferably formed by a lyophilization process.

In contrast, the present invention provides for a device that uses separate fibers that are assembled to form a brush-like structure. This is fundamentally different from the use of a foam as described in Brown. Foams are engineered from a liquid monomer or polymer phase which is mixed with a gaseous agent creating voids and pores upon decompression. Without this process, the polymer would form a solid block material. It is not obvious to a person skilled in the art to transition from a foamed polymer, as provided in Brown, to a separate fibrous polymer, as described in independent claims 1, 30 and 31.

In addition, the specific orientation of the separate fibers distinguishes the claimed present invention. Upon implantation of the prosthetic device, about 90% of the fibers are aligned essentially parallel to the axis of insertion of the prosthetic device and essentially perpendicular to the top surface of the base component. This alignment of the fibers mimics the cartilage and cartilage-like tissues, thus providing excellent mechanical stability. This benefit continues even though the orientation may slightly change during the course of manipulation by the surgeon or under load. Brown does not provide for fibers that are aligned essentially parallel to the axis of insertion of the prosthetic device and essentially perpendicular to the top surface of the base component, as recited in independent claims 1 and 30.

Accordingly, Brown fails to disclose or suggest a prosthetic device having

separate fibers, as provided in claims 1, 30 and 31, along with fibers that are aligned essentially parallel to the axis of insertion of the prosthetic device and essentially perpendicular to the top surface of the base component, as recited in independent claims 1 and 30. Therefore, claims 1, 30 and 31, as well as claims 2-21, 23-29 and 32-33, which depend therefrom, are in condition for allowance.

For example, concerning dependent claims 3-8, the Office Action compares the teachings of Brown regarding porosity to the liquid absorbing capacity described in the present invention. Porosity and liquid absorbing capacity for hydrogel formation are fundamentally different. A 99% porous polypropylene foam has a high capacity to store water or any liquid in its pores, however the water does not interact chemically by hydrogen bridging with the foam. In contrast, the fibers of the present invention are not porous, instead they have the capability of binding water and forming a hydrogel under swelling. This is considered to be a fundamental difference and therefore not obvious in view of Brown.

In addition, the fiber diameter is a broad range since the optimal diameter depends on the polymeric material present, such as a polyhydroxymethacrylate or a hyaluronic acid, each providing different dimensions. The fibers are often intermixed (although the fibers are chemically and physically separated) in the prosthetic device to optimize the mechanical and gelating effects. Brown patent does disclose or suggest these features.

Concerning dependent claims 9-16, the teachings in Brown are know-how that has been described in prior art literature, e.g. Bavaresco et al, in Artificial Organs (2000). In contrast, the ceramic anchoring in combination with the brush-like polymeric fibers of the present invention are essential and not obvious in view of Brown. Furthermore, the cylindrical shape of the anchor is provided by the anatomical and physiological situation upon implantation and mechanical requirements of the prosthetic device of the claimed present invention.

Concerning dependent claims 17-18 and 20, the optimal dimensions of the ceramic anchor depends on the size of the defect, the bone quality and the age of the patient. A prosthetic device of the present invention manufactured according to these dimensions is not obvious over Brown.

Concerning dependent claims 22-27 and 29, the delivery of therapeutic agents and cells by polymer foams or porous ceramic material, as described in Brown, is well known in the art. In contrast, a prosthetic device of the claimed present invention containing fibrous brush-like structures and a component, such as cells concentrates and/or blood fractions added upon implantation, is not obvious over Brown.

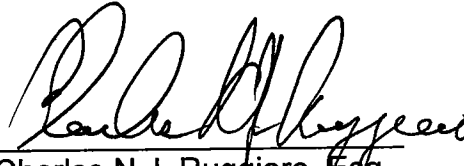
Dependent claim 34 has been added reciting a limitation previously claimed in dependent claim 2. For the same reasons as provided above, it is believed that new claim 34 is in condition for allowance. In particular, claim 34 provides for a prosthetic device where 90% of the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device that is in a direction perpendicular to a top surface of the base component. Brown does not disclose or suggest these features.

In view of the foregoing, Applicant respectfully submits that all claims present in this application patentably distinguish over the cited prior art reference. Accordingly, Applicant respectfully requests favorable reconsideration and withdrawal of the rejection of the claims. Also, Applicant respectfully requests that this application be passed to allowance.

If for any reason the Examiner feels that consultation with Applicant's attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

December 30, 2009

A handwritten signature in black ink, appearing to read "Charles N.J. Ruggiero", written over a horizontal line.

Charles N.J. Ruggiero, Esq.

Registration No. 28,468

Attorney for Applicant

Ohlandt, Greeley, Ruggiero & Perle, L.L.P.

One Landmark Square, 10th floor

Stamford, CT 06901-2682

Tel: (203) 327-4500

Fax: (203) 327-6401